TRANSMITTAL OF APPEAL BRIEF

Docket No.
OSTEONICS 3.0-456

In re Application of: Carlos E. Collazo

Application No.	Filing Date	Examiner	Group Art Unit
10/679,569	October 6, 2003	A. R. Reimers	3732

Invention: REAMER BUSHING

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application.

The fee for filing this Appeal Brief is 500.00 .

[X] Large Entity [ ] Small Entity

[ ] A check in the amount of _____ is enclosed.

[X] Charge the amount of the fee to Deposit Account No. 12-1095 .
This sheet is submitted in duplicate.

[X] The Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 12-1095 .
This sheet is submitted in duplicate.

Dated: February 14, 2006

Raymond W. Augustin
Attorney Reg. No.: 28,588
LERNER, DAVID, LITTENBERG, KRUMHOLZ &
MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 518-6318

LD-546\

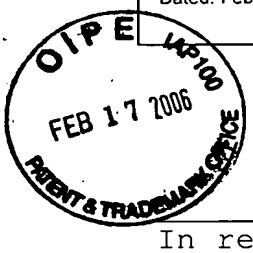
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 14, 2006 Signature: (Raymond W. Augustin)

631639

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 14, 2006 Signature: (Raymond W. Augustin)



Docket No.: OSTEONICS 3.0-456
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Carlos E. Collazo

Application No.: 10/679,569 Group Art Unit: 3732

Filed: October 6, 2003 Examiner: A. R. Reimers

For: REAMER BUSHING

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant hereby files this brief on Appeal to appeal from the final rejection of claims 12-16, 18 and 20-24 mailed August 11, 2005.

REAL PARTY(IES) IN INTEREST

The real party in interest in this case is the assignee of record, Howmedica Osteonics Corp, 59 Route 17, Allendale, New Jersey 07401, as evidenced by the Assignment dated September 23, 2003 and recorded at reel 014590, frame 0559.

RELATED APPEALS AND INTERFERENCES

To the best of the current knowledge of Applellant, there are no related appeals or interferences pending before the

02/17/2006 SFELEKE1 00000104 121095 10679569
625724
01 FC:1402 500.00 DA

United States patent and Trademark Office regarding this United States Patent application.

STATUS OF CLAIMS

Claims 12-16, 18 and 20-24 are pending in the present application. A clean copy of the claims are attached hereto as Appendix A.

STATUS OF AMENDMENTS

The most recent Amendment filed on May 18, 2005 has been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides an instrumentation system for long bone surgery or in any application in which it is desired to enlarge a bore in a bone in a progressive manner. The present invention provides two or more reamers of different diameter in a set, a single rotatable bushing engageable with each of the reamers of the set and a bushing holder for holding the rotatable bushing in fixed alignment with respect to the bore to be reamed and enlarged.

The invention provides a rotatable bushing which can accommodate a series of reamers each having flutes of a different diameter to create different size bores.

The invention is achieved by a kit of tools or instruments for reaming a series of progressively larger bores, which kit has at least two reamers. Each of the reamers has a plurality of flutes extending radially from a central shaft, the flutes of each reamer extend at different radial distances increasing from a smallest diameter reamer to a largest diameter reamer. However, the inner shafts of each reamer from which the flutes

extend have the same diameter. This allows the use of the single rotatable guide bushing of the present invention which has a series of recesses for receiving each of the flutes of the reamers. The number of recesses in the bushing is equal to or greater than the number of flutes on the reamers. The recesses in the guide bushing are open to and extend radially outwardly from a central bore or opening, which central bore has a diameter equal to the constant inner shaft diameter of the reamers. The recesses extend radially from the central bore or opening a distance greater than or equal to the largest radial extent of the flutes of the largest reamer. Thus, each reamer from the smallest to the largest may be inserted within the rotatable bushing and be guided by the engagement between the inner shaft and central bore of the bushing to maintain coaxial alignment with the bore.

A holder is provided which can be fixed and aligned with respect to the bore to be enlarged, such as to the medulary canal of a long bone. The rotatable guide bushing rotates on or with the fixed holder. It can be seen that the rotation of the rotatable bushing is caused by the rotation of the reamer, specifically the rotation of flutes acting against the recesses in the reamer bushing. The reamer, itself, has a drive end which may be driven by any convenient rotary power source such as a pneumatic or electric power drill.

As long as the bushing has a sufficient number of recesses to accommodate the reamer with the largest number of flutes, then reamers with fewer flutes may also be utilized. Of course, the flutes of the reamer must be angularly oriented about the circumference of the reamer at the same angle as the recesses in the bushing. Preferably, the reamer has eight flutes oriented at 45° increments around the circumference of the central shaft. Thus, the preferred bushing would have eight recesses oriented at 45° increments around the central bore. Obviously, more or

fewer flutes can be used as long as the angular spacing of the recesses in the rotatable bushing corresponds to the angular orientation of the flutes. It can be seen that the preferred rotatable bushing is designed to accommodate eight flutes spaced at 45°. However, it could also accommodate a reamer having four flutes spaced at 90°. If the reamer has more than eight flutes, such as, for example, ten flutes, then the spacing of the recesses and the flutes would be at 36° increments around the circumference of the central reamer shaft/central bushing bore.

Furthermore, the reamer bushing could be designed to have at least three recesses for receiving one or more of the reamer flutes. Each recess may receive one, two or even three flutes. In addition, the flutes and reamer bushing recesses may be helically shaped as long as the root diameters of the reamer flutes conforms to the inner bore of the reamer.

The instrumentation is designed for use primarily in enlarging bone canals such as in the femur and tibia. When used in a bone canal, the diameter of the reamers progressively increases in .5, 1 or 2 mm increments. However, when utilized in other materials and in other diameters, the reamer diameters may be incrementally increased in any convenient amount, depending upon load and heat generation limitations.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 12-16, 18 and 20-22 are patentable under 35 U.S.C. § 102(3) or being anticipated by Cenis U.S. Patent No. 3,981,604.

2. Whether claims 12-14, 18 and 20-22 are patentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2003/0163151 to Ball et al.

3. Whether claims 23 and 24 are patentable under 35 U.S.C. § 103(a) as being obvious over Cenis U.S. Patent No. 3,981,604.

ARGUMENT

The Examiner has finally rejected claims 12-16, 18 and 20-22 as being anticipated by Cenis U.S. Patent No. 3,981,604 ("the 604 Patent") and claims 12-14, 18 and 20-22, U.S. Patent Publication 2003/0163151 to Ball et al ("Ball et al."). These two references show non-rotating bushing elements having grooved inner surfaces.

The '604 Patent shows a liner bushing 21 for receiving a locating pin or drill guide. (Col.1 ll.27-32.) The initial paragraph of the '604 Patent describes a liner bushing as being made from hard material which is then used to line an aperture in a softer material tooling plate or the like. The liner bushing may be press-fitted into the aperture or held in the tooling plate by potting in a resinous material. In either case the liner bushing does not rotate. Nor does it receive a rotating tool. The recesses 22 of the liner do not receive any tool.

Claim 12 of the present application requires that the bushing comprises a body with an outer bearing surface for rotatably engaging a surface of the fixture in which the bushing is mounted. The fixture is recited in the claim preamble. This clearly distinguishes over the '604 Patent which has no outer bearing surface for rotatably engaging a fixture. The Examiner has totally ignored the preamble of claim 12 which claims a reamer bushing mounted in a fixture adapted for being aligned with the bone canal for use with at least two different diameter rotatable bone reamers each having a plurality of longitudinal flutes extending from an inner shaft. Obviously, none of the

references related to these limitations in the preamble. It is Appellant's position that the preamble is a positive limitation in the claim and should be used to structurally distinguish over the prior art cited. The bearing surface of the fixture which is aligned with the bone canal and the bone reamers are in the body of the claim and refer back to the preamble for their antecedent basis.

If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning and vitality to the claim then the claimed preamble should be construed as if in the balance of the claim *Pitney Bowes, Inc. v. Hewitt-Packard Co.* 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1165-66 (Fed. Cir. 1999). In addition clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. *See Metabolite Labs, Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62, 71 U.S.P.Q.2d 1081, 1084-87 (Fed. Cir. 2004). None of the prior art cited by the Examiner relates to preparing a bone canal. Furthermore, the body of claim 12 positively recites that the plurality of flutes are part of a bone reamer and the bushing has a bearing surface rotatably engaging the fixture. This further distinguishes from the '604 Patent which is directed to a machine tool not used in orthopedics. Consequently, Appellant considers claim 12, is not anticipated by or obvious over the '604 Patent.

By definition a reamer is a cutting tool which rotates and such rotation would not be possible in the design of the '604 Patent if the flutes of the reamer engaged the grooves 22 of the non-rotatable bushing shown in the '604 Patent. None of the flutes of any cutting member are placed in the grooves 22 of the non-rotating liner bushing 21 as taught in the '604 Patent.

Since none of the bushings in the '604 Patent rotate, it would be impossible to use the bushing 21 with rotatable bone reamers having flutes engaging the recesses or grooves as claimed. Obviously if the liner bushing is press-fit or glued to the plate 14 of the '604 Patent rotation of both the bushing and the reamer would be prohibited if the flutes were positioned within the grooves.

Ball et al. again relates to a non-rotatable housing having a splined inner surface. The splined inner surface receives a non-rotatable actuator which can move axially within the bore of the non-rotatable housing to cause rotation of shaft 41. Shaft 41 is utilized to fracture the excess portion of pin 11. The housing is not mounted in a fixture and is not rotatable. The splines do not receive flutes of a bone reamer.

In Ball et al., there is no bushing disclosed having a body with an outer bearing surface for rotatably engaging a fixture in which the bushing is mounted. The actuator 30 moves only axially within housing cavity 24 and, as described in the top of col. 5 of Ball et al., when actuator 30 is moved within housing 20, the cam members 42 engage the internal grooves 34 of actuator 30 which causes cutting member 40 to rotate and fracture pin 11. There is no rotation of actuator 30 or housing 20. The splines are provided to prevent rotation of actuator 30 in housing 20. There is no relative rotation between the housing 20 and any fixture as claimed in claim 12. There is no reamer designed for use in a bone canal as claimed.

Ball et al. has none of the features claimed in the preamble of claim 12. It does not relate to a bushing with a body having an outer bearing surface for rotating against a surface of a fixture as claimed.

The Examiner then went on to reject claims 23 and 24 as being obvious over the '604 Patent. In addition to the arguments made above with regard to the anticipation rejection

over the '604 Patent, Appellant does not believe one of ordinary skill in the bone canal preparation instrumentation art would look into the machine tool art directed to a non-rotatable slotted bushing where the slots have edges for scraping the accumulated corrosion of off pins and other tools inserted therein or to reduce friction (surface area) between the liner bushing and the slip replaceable bushing. The design of the present invention allows the use of a plurality of different sized bone reamers with a single rotatable bushing. Bone reamers of incrementally increasing size are necessary when progressively enlarging a bone canal. The fact that the bushing rotates with the rotatable bone reamer is not taught or suggested in the '604 Patent

CONCLUSION

It is Appellant's position that claims 12-14, 18 and 20-22 are not anticipated by U.S. Patent Publication 2003/0163151 to Ball et al. nor are claims 12-16, 18 and 20-22 anticipated by Cenis U.S. Patent No. 3,981,604. Neither of these patents disclose every element of the claims such as the rotatable bushing. Nor do any of the patents teach recesses for receiving at least one of the plurality of flutes of the bone reamers. Nor are they designed for use with at least two different diameter rotatable bone reamers as claimed in claim 12. It is Appellant's position that neither of the devise shown in the cited prior art teach or suggest a reamer bushing mounted in a fixture adapted for being aligned with the bone canal with recesses for receiving the flutes of the reamer.

Furthermore, Appellant does not consider that the claims are obvious over Cenis. Cenis teaches the use of a non-rotating device with splines which do not receive any part of a reaming

instrument. This teaching cannot render claims directed to a bone reaming instrument obvious.

Thus, it is Appellant's position that none of the claims are either anticipated or rendered obvious by the art cited by the Examiner.

Dated: February 14, 2006

Respectfully submitted,

By _____
Raymond W. Augustin
Registration No.: 28,588
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Appellant

APPENDIX A - CLAIMS

Claims 1-11 (cancelled).

12. (currently amended) A reamer bushing mounted in a fixture adapted for being aligned with a bone canal, the bushing for use with at least two different diameter rotatable bone reamers, the reamers each having a plurality of longitudinal flutes extending from an inner shaft, outer radial ends of the flutes defining the reamer diameter, the bushing comprising:

a body with an outer bearing surface for rotatably engaging a surface of the fixture in which the bushing is mounted;

a longitudinal bore formed in the body for receiving the inner shaft of the reamer; and

a plurality of recesses extending radially outward of said bore and open thereto, each recess for receiving at least one of said plurality of flutes of said bone reamers.

13. (currently amended) The reamer bushing as set forth in claim 12 wherein said recesses extend radially from said bushing body longitudinal bore a distance greater than a largest radial extent of the flutes of the at least two reamers.

14. (currently amended) The reamer bushing as set forth in claim 13 wherein the bushing has a number of recesses equal to or greater than the plurality of flutes on each of said reamers.

15. (currently amended) The reamer bushing as set forth in claim 12 wherein said recesses expand in width on moving radially outwardly from said bushing body longitudinal bore.

16. (currently amended) The reamer bushing as set forth in claim 15 wherein said reamer flutes expand in width in moving radially outwardly from said inner shaft.

17. (cancelled).

18. (original) The reamer bushing as set forth in claim 12 wherein said bushing has at least three recesses formed therein.

19. (cancelled)

20. (previously presented) The reamer bushing as set forth in claim 12 wherein said recesses each receive at least two flutes.

21. (currently amended) The reamer bushing as set forth in claim 12 wherein the bushing body is cylindrical and said outer bearing surface extends circumferentially around an outer cylindrical surface of the bushing.

22. (previously presented) The reamer bushing as set forth in claim 21 wherein said cylindrical outer bearing surface extends about an axis which is coaxial with an axis of said longitudinal bore.

23. (previously presented) The reamer bushing as set forth in claim 22 wherein said plurality of recesses have radial ends opposite ends thereof open to said bore at a shorter radial distance from said axis of said longitudinal bore than said outer cylindrical surface of the bushing.

24. (currently amended) The reamer bushing as set forth in claim 23 wherein said recesses expand in width on moving radially outwardly from said bushing body longitudinal bore.

APPENDIX B - EVIDENCE

Appellant has not submitted any evidence with this Appeal Brief.

APPENDIX C - RELATED PROCEEDINGS

Appellant is not aware of any related proceedings.